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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,847	11/23/2005	Charles Henry Horn	05-037	1275
20306	7590	12/12/2007	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP			ARIANI, KADE	
300 S. WACKER DRIVE			ART UNIT	PAPER NUMBER
32ND FLOOR			1651	
CHICAGO, IL 60606			MAIL DATE	DELIVERY MODE
			12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/521,847	HORN ET AL.
	Examiner Kade Ariani	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 October 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 23,24 and 26-57 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 23,24 and 26-57 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    - a) All    b) Some \* c) None of:
      1. Certified copies of the priority documents have been received.
      2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
      3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***DETAILED ACTION***

The amendment filed on 10/01/2007, has been received and entered.

Claims 1- 22 and 25 have been canceled.

Claims 23, 24, and 26-57 are pending in this application and were examined on their merits.

***Claim Objection***

Claim 55 is objected to because of the following informalities:

The word --lasalocid-- is misspelled as "lasalosid" in the specification (page 4, line 12).

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 23, 26, and 40 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn due to applicants amendments to the claims filed on 10/01/07.

Claims 51-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Claims 51-57 recite the limitation "the method according to claim 42". There is insufficient antecedent basis for this limitation in the claims.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 23-39 under 35 U.S.C. 101, because the claimed invention is directed to non-statutory subject matter, is withdrawn due to applicants amendments to the claims filed on 10/01/07.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 23 and 40-47 under 35 U.S.C. 102(b) as being anticipated by Leedle et al. (US Patent No. 5,380,525, issued Jan. 10, 1995), is withdrawn due to applicants amendments to the claims filed on 10/01/07.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23, 24, and 26-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leedle et al. (US Patent No. 5,380,525, issued Jan. 10, 1995).

Claims 23, 24, and 26-57 are drawn to a composition comprising a biologically pure bacterial culture of *M. elsdenii* strain 41125, growth rate of at least  $0.938 \text{ h}^{-1}$ , a method comprising administering to the rumen of ruminants an effective amount of the composition, ruminal lactic acidosis, a method of isolating a biologically pure culture of *M. elsdenii* comprising obtaining a sample of ruminal fluids and cultivating the sample on a growth medium, a composition comprising a bacterial culture of *M. elsdenii*, and a method of treating comprising administering an effective amount of that composition, and ruminal lactic acidosis.

Leedle et al. teach a biologically pure bacterial culture of *M. elsdenii* (see claim 1). In general organisms sharing more than 97% ribosomal RNA similarity may belong to a single species and since the biologically pure bacterial culture disclosed by Leedle et al. belongs to a *M. elsdenii* species therefore, it must display at least 97% similarity to a 16S ribosomal RNA (rRNA) sequence with the claimed bacterial strain and the same lactate-degrading abilities which are important in controlling acidosis by removing lactic acid through catabolic action.

Leedle et al. teach the bacterium consumes lactic acid, is resistant to monensin (ionophore), lasalocid, and low pH (5.3) (column 2, lines 27-30), ability to utilize 80% of lactate in the presence of sugars (column 8, lines 36-38), and a composition and a method for facilitating the adaptation of ruminants from a roughage-based diet to high energy concentrate-based diet (see abstract and column 1).

Leedle et al. further teach a method of isolating and a culture of a ruminal microorganism comprising obtaining a sample of ruminal fluids and cultivating the sample on a growth medium, a method of preventing acute lactic acidosis comprising administering an effective amount of a bacterial culture of *M. elsdenii* (see abstract, claims 1-4, columns 2 and 3, Example 1).

Leedle et al. do not teach strain 41125, and a growth rate of at least  $0.938\text{ h}^{-1}$ . However, at the time the invention was made it was very well known in the art that different strains of *M. elsdenii* were able to prevent lactate accumulation and excessive drop in pH in ruminal fermentation.

Applicant's arguments with respect to claims 23, 24, and 26-57 filed on 10/01/07 have been fully considered but they are not persuasive.

Applicant argues that claim 23 has been amended to reflect that growth rate fro the microorganism is  $0.938\text{ h}^{-1}$ , and an organism with this growth rate is not taught or suggested by Leedle et al.

However, Leedle et al. teach comparison of *M. elsdenii* strains growth curves and consumption of lactate and glucose showed that all strains grew faster or at a faster rate than other rumen bacteria, and further teach their faster growth rates might enable them to better compete in the rumen (column 11, lines 50-55 and 63-64).

Leedle et al. further teach strains were selected for further evaluation as potential acute acidosis preventatives based on the results of the in vitro lactic acid acidosis tests, strain growth rates, and MIC (minimal inhibitory concentration) data (column 12, lines 10-13).

Therefore, at the time the invention was made it would have been obvious to one of ordinary skill in the art to use the teachings and the method of Leedle et al. in order to obtain a biologically pure bacterial culture of *M. elsdenii* and provide a composition comprising a biologically pure bacterial culture of *M. elsdenii* and administering an effective amount of that composition to the rumen of a ruminant for the treatment of ruminal lactic acidosis. One would have been motivated to do so, since at the time the invention was made, lactate-degrading abilities of several strains of *M. elsdenii* and the method for isolating such strains were very well known in the art, also several strains of *M. elsdenii* were being used for the same purpose. Moreover, as taught by Leedle et al.

comparison of *M. elsdenii* strains growth curves and consumption of lactate and glucose showed that all strains grew faster or at a faster rate than other rumen bacteria, therefore their faster growth rates might enable them to better compete in the rumen, thus one would have been motivated to obtain a strain of *M. elsdenii* which has a faster growth rate on lactic acid.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

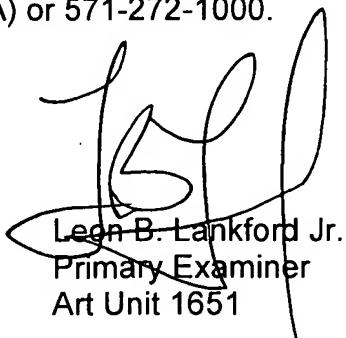
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1651



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